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10/553,374	08/21/2006	Catherine Le Hen Ferrenbach	C 2823 PCT/US	3681

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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary	Application No.	Applicant(s)	
	10/553,374	LE HEN FERRENBACH ET AL.	
	Examiner	Art Unit	
	MICHELE FLOOD	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the preliminary amendment filed on October 14, 2005 with the cancellation of Claims 1-11 and the addition of newly added Claims 12-24.

Claims 12-24 are under examination.

Specification

The disclosure is objected to because the specification recites "new" on page 1, line 3 and line 24. It is suggested that the term "new" be deleted from the language of the specification. Once the determination of the novelty of a claimed invention has been established and the disclosure of the invention made public and/or patented, the claimed invention is no longer novel or new, since the scope of the invention no longer embraces what is considered "new". Thus, the incorporation of the term "new" into the language of the specification is not appropriate.

Please note that the Examiner has attempted to provide all instances wherein the specification recites the term "new". However, the specification must be carefully read to identify and eliminate any occurrence of the term "novel" or "novelty" or "new" from the specification.

Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 18, 19 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "the A2 type of proanthocyanidin" in line 1. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by deleting "of the", and adding an.

The metes and bounds of each of Claims 18 and 19, line 1, are rendered indefinite by the phrase "from about" because the simultaneous recitation of "from" and "about" fails to provide any specific indication as to what range of numerical value is covered by "from about". The lack of clarity renders the claims ambiguous.

The metes and bounds of Claim 22 are rendered vague and indefinite, as presently drafted in its entirety, because while the preamble recites "A method of using a composition for oral administration", the body of the claim recites subject matter directed to "which method incorporating into a food product said composition as an additive". In other words, the claim language of the body is not commensurate in scope to the preamble of the claim. For instance, what does "A method of using a composition for oral administration" have to do with 'incorporating the claim-designated additive composition into a food product'? Moreover, the "which" clause directly following the preamble does not recite any

active process steps *per se*; and the second "which" clause merely recites what comprises the claim-designated additive composition. Thus, the claim fails to recite any additional active method steps, but simply states a characterization of ingredients and experimental parameters intended for use in an implied method to result the claimed method. The lack of clarity of Claim 22 is further exacerbated by Claims 23 and 24 which encompass claim language reciting "wherein" clauses (for example, Claim 23 recites "wherein the food product is for reducing body fat in a mammal"; and Claim 24 recites "wherein the food product is for regulating the moisture content of skin". The MPEP 2111.04 states, "Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure. Given the foregoing, it is uncertain as to the subject matter to which Applicant intends to seek patent protection. However, for the purposes of expeditious examination of the claims on the merits, Claim 22 has been interpreted as reading on a method of making a food product comprising incorporating the claim-designated additive composition into a food product.

All other cited claims depend directly or indirectly from rejected claims; and, therefore, are also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 12-14, 16-18, 20 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ghisalberti et al. (IDS: WO 01/17374 A1).

Applicant claims a composition for oral administration comprising: (a) a physiologically active fatty acid containing about 16 to 26 carbon atoms and

about 2 to 6 double bonds, and esters or glycerides thereof; and (b) an oligomeric proanthocyanidin or a plant extract containing said proanthocyanidin. Applicant further claims the composition of claim 12, wherein component (a) is a conjugated linoleic acid and esters or glycerides thereof. Applicant further claims the composition of claim 13, wherein the conjugated linoleic acid contains at least 30% by weight t10,c12 isomers, at least 30% by weight c9,t11 isomers and less than 1% by weight 8,10-, 11,13- and t,t-isomers. Applicant further claims the composition of claim 12 wherein the oligomeric proanthocyanidin is of the A2 type of proanthocyanidins; wherein the plant extract of component (b) is selected from the group of plants consisting of *Camellia sinensis*, *Pinia silvestris*, *Vitis vinifera*, *Litchi chinensis*, *Potentille erecta* and mixtures thereof; and wherein components (a) and (b) are present in a ratio by weight of from about 90:10 to about 10:90. Applicant further claims the composition of claim 12 which is provided in an encapsulated form.

Applicant claims method of using a composition for oral administration, which method comprises incorporating into a food product said composition as an additive, which composition comprises: (a) a physiologically active fatty acid containing about 16 to 26 carbon atoms and about 2 to 6 double bonds, and esters or glycerides thereof; and (b) an oligomeric proanthocyanidin or a plant extract containing said proanthocyanidin. Applicant further claims the method of claim 22 wherein the food product is for reducing body fat in a mammal; and wherein the food product is for regulating the moisture content of skin.

On page 20 (Example 2), Ghisalberti teaches compositions for oral administration, in encapsulated form, for reducing body fat in a mammal (including humans), comprising conjugated linoleic acid and *Vitis vinifera* extract proanthocyanidins. On page 7, lines 6 and 7, pine bark (*Pinia silvestris*) is also suggested as a plant source of proanthocyanidins for use in the reference compositions. Ghisalberti further teaches, "The composition of CLA appears to a be a complex of mixture, i.e. 9c,11t- and 8c,10t- octadecadienoic acids at 30.90%, 11c,13t- 10t,12c-octadecadienoic acids at 32.05%, 11,13c- 8c,10c- 9c,11c- octadecadienoic acid at 1.55%, 10c,12c-, 11c,13c-, 11t,13t, 9t,11t,10t,12t-8t,10t-octadecadienoic acids making the remaining part. The compositions taught by Ghisalberti are considered food grade antioxidants which can be incorporated into food products, such as food or drinks, baby-food, functional foods and animal foods.

With regard to Claims 22 and 24, Applicants' claims recite a which clause that appears immediately after the preamble, which is not given any patentable weight because it simply expresses the intended result of the process step positively recited in steps a and b of the claims, hence the prior reads on the claims, see MPEP 2111.01 [R-3]. Moreover, the clause does not recite any additional active method steps, but simply states a characterization or conclusion of the results of those steps. Applicant's active step recites '[which method comprises] incorporating into a food product said composition as an additive", [which composition comprises] (a) . . . ; and (b) . . .". This reference reads on Applicants' active step listed in Claim 22 and hence reads on the claimed

method. Applicants' attention is directed to MPEP 2106 in which statements of intended use or field of use are examples of language that may raise a question as to the limiting effect of the language in a claim. The MPEP 2111.02 notes "statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the clams of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim." In the instant case, the alleged second step or characterization of the claimed method of Claim 24, correlating a food product for regulating the moisture content of skin with a method of using a composition for oral administration by incorporating as a food additive a composition which comprises (a) a physiologically active fatty acid containing about 16 to 26 carbon atoms and about 2 to 6 double bonds, and esters or glycerides thereof; and (b) an oligomeric proanthocyanidin or a plant extract containing said proanthocyanidins does not appear to be a manipulative step, hence the rejection is invoked herein since the expressed beneficial functional effect for regulating moisture content of the skin would be an inherent feature of the oral food product since Applicant's disclosed food product comprises one and the same ingredients comprising the prior art composition produced by one and the same method as claimed by Applicant.

The reference anticipates the claimed subject matter.

Claims 12-14, 16-18 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Hastings et al. (IDS: US 2001/0041187 A1).

Applicant's claimed invention was set forth above.

At [0026], Hastings teaches a composition for oral administration comprising 2.7% conjugated linoleic acid (Tonalin®) and 0.2% A2-type oligomeric proanthocyanidins-containing grape seed (*Vitis vinifera*) extract (ActiVin®), which is used as a dietary supplement. At [0027], Hastings further teaches incorporating the dietary supplement into a food product, such as water, juice or milk.

With regard to Claims 22-24, Applicants' claims recite a which clause that appears immediately after the preamble, which is not given any patentable weight because it simply expresses the intended result of the process step positively recited in steps a and b of the claims, hence the prior reads on the claims, see MPEP 2111.01 [R-3]. Moreover, the clause does not recite any additional active method steps, but simply states a characterization or conclusion of the results of those steps. Applicant's active step recites '[which method comprises] incorporating into a food product said composition as an additive", [which composition comprises] (a) . . . ; and (b) . . .". This reference reads on Applicants' active step listed in Claim 22 and hence reads on the claimed method. Applicants' attention is directed to MPEP 2106 in which statements of intended use or field of use are examples of language that may raise a question as to the limiting effect of the language in a claim. The MPEP 2111.02 notes "statements in the preamble reciting the purpose or intended use of the claimed

invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the clams of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim." In the instant case, the alleged second steps or characterization of the claimed method of Claims 23 and 24, correlating a food product for reducing body fat in a mammal or for regulating the moisture content of skin with a method of using a composition for oral administration by incorporating as a food additive a composition which comprises (a) a physiologically active fatty acid containing about 16 to 26 carbon atoms and about 2 to 6 double bonds, and esters or glycerides thereof; and (b) an oligomeric proanthocyanidin or a plant extract containing said proanthocyanidins does not appear to be a manipulative step, hence the rejection is invoked herein since the expressed beneficial functional effect for reducing body fat in a mammal or for regulating moisture content of the skin would be an inherent feature of the oral food product since Applicant's disclosed food product comprises one and the same ingredients comprising the prior art composition produced by one and the same method as claimed by Applicant.

The reference anticipates the claimed subject matter.

Claims 12, 13, 15- 20 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Merizzi (IDS: WO 01/19381 A2).

Applicant's claimed invention of Claims 12, 13, 16-18, 20 and 22- 24 was set forth above. Applicant further claims the composition of claim 12 wherein

component (a) is an omega-3 fatty acid. Applicant further claims the composition of claim 18 wherein components (a) and (b) are present in a ratio by weight of from about 60:40 to 40:60.

Merizzi teaches an oral composition comprising omega-3-fatty acids and oligomeric proanthocyanidin-containing grape seed (*Vitis vinifera*) extract, which can be in the form of a gelatin capsule. *See* Table on page 8-9. On page 9, lines 6-11, Merizzi teaches that the reference compositions can be incorporated into an edible vehicle or can be incorporated into food as part of a diet.

With regard to Claims 22-24, Applicants' claims recite a which clause that appears immediately after the preamble, which is not given any patentable weight because it simply expresses the intended result of the process step positively recited in steps a and b of the claims, hence the prior reads on the claims, see MPEP 2111.01 [R-3]. Moreover, the clause does not recite any additional active method steps, but simply states a characterization or conclusion of the results of those steps. Applicant's active step recites '[which method comprises] incorporating into a food product said composition as an additive", [which composition comprises] (a) . . . ; and (b) . . .". This reference reads on Applicants' active step listed in Claim 22 and hence reads on the claimed method. Applicants' attention is directed to MPEP 2106 in which statements of intended use or field of use are examples of language that may raise a question as to the limiting effect of the language in a claim. The MPEP 2111.02 notes "statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or

intended use results in a structural difference (or, in the clams of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim." In the instant case, the alleged second steps or characterization of the claimed method of Claims 23 and 24, correlating a food product for reducing body fat in a mammal or for regulating the moisture content of skin with a method of using a composition for oral administration by incorporating as a food additive a composition which comprises (a) a physiologically active fatty acid containing about 16 to 26 carbon atoms and about 2 to 6 double bonds, and esters or glycerides thereof; and (b) an oligomeric proanthocyanidin or a plant extract containing said proanthocyanidins does not appear to be a manipulative step, hence the rejection is invoked herein since the expressed beneficial functional effect for reducing body fat in a mammal or for regulating moisture content of the skin would be an inherent feature of the oral food product since Applicant's disclosed food product comprises one and the same ingredients comprising the prior art composition produced by one and the same method as claimed by Applicant.

The reference anticipates the claimed subject matter.

Claims 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Leach (IDS: US 5,612,074).

Applicant's claimed invention was set forth above.

In Column 5, lines 9-41 teaches, "The ingredients of the food bar of the present invention are selected so that the food bar contains about 35% by weight

of complex carbohydrate and about 17% by weight of simple carbohydrate. Considering both the oil seeds of the mixture of dry ingredients and the vegetable oil of the mixture of liquid ingredients, polyunsaturated linoleic acid is present in the food bar in a ratio of about 3:1 by weight to superunsaturated alpha-linolenic acid. Preservation of polyunsaturated linoleic acid and superunsaturated alpha-linolenic acid, and thereby maintenance of the desired ratio of polyunsaturated linoleic acid to superunsaturated alpha-linolenic acid, is improved by presence of the antioxidants, with dimeric proanthocyaniden as provided by sorghum syrup, and vitamin E oil believed to be particularly important in such preservation. The food bar of the present invention may be formed of any convenient size and weight, with a weight of approximately 2.25 ounces (about 62 grams) particularly advantageous. The caloric content in a 2.25 ounce food bar is less than 250 calories, and the ingredients provide a food bar having no cholesterol and saturated fat of less than 1.2 grams. In addition, the food bar of the present invention provides about 7 grams of polyunsaturated linoleic acid and about 2 grams of superunsaturated alpha-linolenic acid, satisfying the recommended daily allowance, RDA, of polyunsaturated linoleic acid and of superunsaturated alpha-linolenic acid. Further, moisture content in the food bar of the present invention is maintained at about 10%, thereby providing a balance between dry, fibrous mouth feel associated with insufficient moisture and shortened shelf life associated with moisture content above 14%. The food bar of the present invention may be placed into any of a variety of opaque freshness preserving wrappings, including modified atmospheric packaging."

The reference anticipates the claimed subject matter.

Claims 12 and 15-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Clayton (A*).

Applicant's claimed invention was set forth above.

Clayton teaches an oral food additive composition comprising (a) an omega-3 fatty acid; and (b) an oligomeric A2-type proanthocyanidins derived from pine (Pycnogenol) or grape seed extract (Vitis vinifera), wherein components (a) and (b) are present in a ratio by weight, as disclosed by Applicant. *See* [0032] ad [0034]. Also see patent claims.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-14 and 16-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Ghisalberti et al. (IDS: WO 01/17374 A1) in view of Garces et al. (IDS: US 6,534,091 B1).

Applicant's claimed invention of Claims 12-14 and 16-19 was set forth above. Applicant further claims the composition of claim 20 which is provided in a microencapsulated form.

The teachings of Ghisalberti are set forth above. Ghisalberti teaches the claimed invention except wherein the composition is provided in a microencapsulated form. However, modification of the pharmaceutical form of the composition taught by Ghisalberti as disclosed by Applicant to provide the

instantly claimed invention would have been obvious to one ordinary skill in the art because at the time of the invention Garces taught a microcapsule for the encapsulation of active principles having advantages over prior art microcapsules. *See* Column 1, line 64 to Column 2, line 6. At the time the invention was made, one of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success to modify the pharmaceutical form of the composition taught by Ghisalberti per the teachings of Garces to provide the claimed invention because to do so would provide an alternative pharmaceutical form of the Ghisalberti' composition in the form of a microcapsule having improved stability and allowing for the controlled release of the active principle components contained therein via oral administration.

The reference does not specifically teach using the claim-designated ratio of ingredients claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The references teach that the ratio amount of the ingredients can be varied. Thus, the references recognize that the amount of these ingredients can be modified. Therefore, it would have been customary for an artisan of ordinary skill to determine the optimal amount of the ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this

optimization of ingredient amounts or ratio would have been obvious at the time of applicant's invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 12, 13, 15- 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Merizzi (IDS: WO 01/19381 A2) in view of Garces et al. (IDS: US 6,534,091 B1).

Applicant's claimed invention was set forth above.

The teachings of Merizzi are set forth above. Merizzi teaches the claimed invention except wherein the composition is provided in a microencapsulated form. However, modification of the pharmaceutical form of the composition taught by Merizzi as disclosed by Applicant to provide the instantly claimed invention would have been obvious to one ordinary skill in the art because at the time of the invention Garces taught a microcapsule for the encapsulation of active principles having advantages over prior art microcapsules. *See* Column 1, line 64 to Column 2, line 6. At the time the invention was made, one of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success to modify the pharmaceutical form of the composition taught by Merizzi per the teachings of Garces to provide the claimed invention because to do so would provide an alternative pharmaceutical form of the Merizzi' composition in the form of a microcapsule having improved stability and

allowing for the controlled release of the active principle components contained therein via oral administration.

The reference does not specifically teach using the claim-designated ratio of ingredients claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The references teach that the ratio amount of the ingredients can be varied. Thus, the references recognize that the amount of these ingredients can be modified. Therefore, it would have been customary for an artisan of ordinary skill to determine the optimal amount of the ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amounts or ratio would have been obvious at the time of applicant's invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

PAIR system, applicants may be referred to the Electronic Business Center (EBC) at **http://www.uspto.gov/ebc/index.html** or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE FLOOD whose telephone number is (571)272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
June 20, 2010

/Michele Flood/
Primary Examiner, Art Unit 1655